In re Application of Joseph Pilarski Application No. 10/691,145

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### **REMARKS**

Reconsideration of the allowability of the present application in view of the above claim amendments and the following remarks is requested respectfully.

The applicant acknowledges that the Examiner considers that claim nos. 4 to 6, 8, 9 and 12 to 20 contain allowable subject matter.

A certified copy of the Canadian priority application no. 2,409,375 (filed October, 23, 2002) is enclosed.

#### Discussion of the Amendments

Claim 4 has been amended to recite an independent claim and to incorporate the recitations of claims 1 and 3. The recitation of canceled claim 2 has been incorporated into claim 11. Other recitations from amended claim 11 are now found in new claim 21. Support for these amendments is found, for example, in the originally filed claims.

Claims 7, 12 and 13 have been amended to insert recitations as suggested by the Examiner.

Claims 6 to 16 and 18 to 20 have been amended to revise claim dependencies, correct typographical errors and/or to more particularly claim the invention. It is submitted that no new matter has been added by these amendments which are supported by the specification.

### Discussion of the Claims

Claims 1-3 have been canceled. Claims 4, 6 to 9, 11 to 15 and 18 to 20 have been amended. Claim 21 has been added. The claims presently pending are Claims 4 to 21.

# **Claim Objections**

Claims 1, 4, 6 to 9, 11 to 13, 18 and 19 were objected to because of alleged informalities. Claim 1 has been deleted, making the Examiner's objection to "c)" and "d)" moot.

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As suggested by the Examiner, in claim 4, the phrase "the amount of sugar and rate of release of sugar in food in the subject" on lines 3 to 4 has been replaced with "an amount of sugar released and rate of release of sugar by food in the subject."

Also in claim 4, "the amount of sugar and rate of removal of sugar by insulin in the subject" on lines 4 to 5 has been replaced by "an amount of sugar removed and rate of removal of sugar by insulin in the subject."

The Examiner suggested that in claim 6, the step labels "a)" through "c)" should be replaced with "c)" through "e)" to distinguish the steps from those in claim 1. Step labels have been deleted. To the extent that any order of steps is mandatory, the order will be readily apparent to a person skilled in the art. Step labels have also been deleted from claims 8, 16, 18 and 19.

The word "standard" has been deleted from line 2 of claim 7 and line 2 of claim 12.

In claim 9, at line 1, "the insulin" has been replaced with "insulin".

In claim 11, "food" has been replaced with "carbohydrate" rather than change the dependency as suggested by the Examiner.

On line 1 of claim 12, "a time schedule" has been replaced with "a first time schedule" and on line 3 "a time schedule" has been replaced with "a second time schedule".

The dependency of claim 13 has been amended to refer to claim 12. Also in claim 13, "the time schedule" has been replaced with "the first time schedule".

### Claim Rejections - 35 U.S.C. §112

Claims 3 to 5 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 was rejected for using the phrase "the sugar metabolism resulting from the provided unit value" and "sugar metabolism resulting from the insulin units or food units". The Examiner stated that it is unclear how sugar metabolism results from a value or a number of units of a substance. Claim 3 has been deleted. Similar wording is present in amended claim 4. It is

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comparable to a dose amount. For example, claim 4 refers to the provided insulin unit value representing an amount of insulin intended for intake by the subject. The carbohydrate unit value represents an amount of carbohydrate intended for intake by the subject. Sugar metabolism is determined for the amount to be taken in which is represented by units. The claimed methods refer to methods that involve actual measurements of blood sugar levels as well as projected blood sugar levels. The current wording is necessary to protect the full scope of the invention.

The Examiner also objected that claim 3 recites determining the balance value based on "sugar metabolism resulting from the insulin units or food units", however, "the insulin units" in claim 3 appears to refer back to "the balance value of either insulin units or carbohydrate units" of claim 1, thus allegedly making it unclear how the balance value of the insulin units may be determined based on a value resulting from itself. The corresponding wording in claim 4 has been amended to recite "sugar metabolism resulting from insulin or carbohydrate" to clarify that the balance value of the insulin units is not determined based on a value resulting from itself.

The Examiner also objected to the use of the term "food units" in claim 3 because it is unclear what the difference is between "carbohydrate unit" value and a "food unit" value since food units are also described to be intended carbohydrate values. Food units are an alternate way of representing carbohydrate units. For example, a slice of toast or bread can be a food unit as stated in claim 11. Diabetic subjects sometimes find it easier to work with food units, such as a slice of bread or toast, than grams of carbohydrates (examples of food units are provided in Figure 1 onward).

Accordingly, applicant respectfully requests that the rejection of claims 3 to 5 under 35 U.S.C. §112, second paragraph, be withdrawn.

## Claim Rejections – 35 U.S.C. §102

Claims 7, 10 and 11 stand rejected under 35 U.S.C. §102(b) as anticipated by US patent No. 5,997,475 to Bortz. Claims 7, 10 and 11 have been amended to depend from claim 4, which was considered by the Examiner to be novel. Accordingly, applicant respectfully requests that

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the rejections to claims 7, 10 and 11 under 35 U.S.C. §102(b) in view of US patent No. 5,997,475 be withdrawn.

Claim 7 stands rejected under 35 U.S.C. §102(e) as being anticipated by US patent application No. 2002/0107476 to Mann et al. Claim 7 now depends from claim 4, which was considered by the Examiner to be novel. Accordingly, applicant respectfully requests that the rejections to claim 7 under 35 U.S.C. §102(e) as being anticipated by US patent application No. 2002/0107476 be withdrawn.

The applicant does not acquiesce that any amendments or cancellations were made in view of prior art and reserves the right to pursue any canceled claims in a divisional application.

## Conclusion

In view of the above amendment and remarks, an early and favorable Action is requested respectfully.

The commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 19-5425.

Respectfully submitted,

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